HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1191 Medication Synchronization
SPONSOR(S): Health Innovation Subcommittee, Cruz
TIED BILLS: **IDEN./SIM. BILLS:** SB 800

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	14 Y, 0 N, As CS	Langston	Poche
2) Insurance & Banking Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Medication synchronization is the process of a pharmacy coordinating all of a patient's prescription medications to fill them on the same date each month. In order to achieve this, some medications may need an early or short refill to align all the prescription medications. Recently, several states have enacted laws that require health insurance plans to make partial supplies of prescriptions available to consumers at a reduced cost-sharing amount for medication synchronization purposes. Currently, Florida does not require health plans to make partial supplies of prescriptions available to consumers at a reduced cost-sharing amount for medication synchronization.

CS/HB 1191 requires certain health insurers and HMOs to offer medication synchronization services on all policies entered into or renewed on or after January 1, 2018. The medication synchronization services must allow an insured or subscriber to align refill dates of his or her covered prescription drugs at least once per year.

The bill limits the types of prescription drugs are eligible for a partial refill under medication synchronization. It prohibits a partial fill to align refill dates for controlled substances, prescription drugs dispensed in unbreakable packages, and multi-dose units of prescription drugs.

Health insurance policies and HMO contracts that provide prescription drug coverage must cover a partial supply of a covered prescription medication dispensed by a network pharmacy at a prorated cost-sharing for medication synchronization. They must also pay the pharmacy in full for each prescription dispensed, unless otherwise agreed to at the time an insured or subscriber requests medication synchronization.

The bill will have an indeterminate fiscal impact on the State Group Insurance Program and no fiscal impact on local governments.

The bill provides an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Medication Synchronization

Medication synchronization is the process of a pharmacy coordinating all of a patient's prescription medications to fill them on the same date each month.[1] In order to achieve this, some medications may need an early or short refill to align all of the patient's prescription medications.[2] Without medication synchronization, pharmacy workflow operates around patients bringing in new prescriptions, calling for medication refills, and picking up their mediations at their convenience, with those who are on multiple medications often visiting the pharmacy many times a month, which creates inefficiency for the patient and the pharmacy.[3] Medication synchronization programs can reduce the administrative burden on patients who take multiple medications by centering all prescription refills to a common monthly or quarterly fill date.[4] Medication synchronization may also offer pharmacies a mechanism to improve workload and inventory control.[5]

Medication Synchronization in Other States

Recently, several states have enacted laws that require health insurance plans to make partial supplies of prescriptions available to consumers at a reduced cost-sharing amount for medication synchronization purposes. In 2015, Arizona enacted a law that requires pharmacies to dispense an early refill or a short fill and to prorate the cost for a refill for less than the standard refill amount if such a refill is for medication synchronization[6]. It defines medication synchronization as, "the coordination of medication refills for a patient taking two or more medications for a chronic condition that are being dispensed by a single contracted pharmacy to facilitate the synchronization of the patient's medications for the purpose of improving medication adherence." Maine,[7] New Mexico,[8] and Washington[9] enacted similar measures in 2015. Kentucky[10] and Oregon[11] also enacted similar measures in 2015; however, they placed limits on which medications were subject to the new laws, prohibiting early and short refills of Schedule II and certain Schedule III controlled substances.

In 2016, Missouri enacted similar medication synchronization legislation, which also required the health insurance carrier or managed care plan to pay a full dispensing fee to the pharmacy for any prescription dispensed in a quantity less than the prescribed amount to align prescriptions.[12] Ohio also enacted a medication synchronization law in 2016; in addition to prohibitions on Schedule II controlled

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[1] National Community Pharmacist Association, *Model Legislation: Patient Protection & Medication Synchronization*, available at: http://www.ncpa.co/pdf/state/med-synch-model-legislation.pdf (last visited March 25, 2017).
[2] Id.
[3] American Pharmacists Association Foundation, *Pharmacy's Appointment Based Model: A prescription synchronization program that improves adherence*, Jul. 2015, available at: https://naspa.us/wp-content/uploads/2015/07/ABMWhitePaper-FINAL-201309233.pdf (last visited March 22, 2017).
[4] Academy of Managed Care Pharmacy, *Medication Synchronization*, 2015, p. 1, available at: http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=20019 (last visited March 25, 2017).
[5] National Association of Boards of Pharmacy, *Report of the Task Force on Medication Synchronization*, 2016, p. 2, available at: https://nabp.pharmacy/wp-content/uploads/2016/07/MedSynchTFReport-Final.pdf (last visited March 25, 2017).
[6] Ariz. Rev. Stat. ss. 20-848; 20-1057.15; 20-1376.07; 20-1406.07.
[7] Me. Rev. Stat. tit. 24-A s. 2769.
[8] N.M. Stat. ss. 59A-22-1978; 59A-23-1978.
[9] Wash. Rev. Code ss. 48.43; 41.05.
[10] Ky. Rev. Stat. s. 304.17A-165.
[11] 2014 Or. Laws ch. 25, ss. 2; 4.
[12] Mo. Rev. Stat. s. 376.379.

substances, it also limits the number of times a consumer may synchronize his or her medications to once per year.[13]

Federal Health Care Requirements

Patient Protection and Affordable Care Act

The Patient Protection and Affordable Care Act (PPACA)[14] created many new health insurance requirements, including required essential health benefits (EHB) and cost-sharing limits.[15] PPACA requires insurers and HMOs of qualified health plans (QHPs) to provide coverage of EHBs in at least 10 specified categories, including prescription drugs.[16] To be certified as a QHP, the insurer or HMO must submit an application, follow established limits on cost sharing, and be certified by the federal Health Insurance Marketplace.[17]

QHPs must provide access to prescription drug benefits. An individual or small group health plan[18] must allow enrollees to obtain prescription drug benefits at in-network retail pharmacies, unless a drug is subject to restricted distribution by the U.S. Food and Drug Administration; or requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy. A QHP has the flexibility to charge a lower cost-sharing amount when obtaining the drug at an in-network retail pharmacy[19] and only needs to provide enrollees with the option to access drugs that are not exempted at a network retail pharmacy.[20]

Federal law does not require health insurers and HMOs to make partial supplies of prescriptions available to consumers at a reduced cost-sharing amount for medication synchronization.

Medicare Part D

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003[21] established a voluntary, outpatient, prescription drug benefit under Medicare Part D, effective January 1, 2006. Medicare Part D provides coverage through private prescription drug plans that offer only drug coverage, or through Medicare Advantage prescription drug plans that offer coverage as part of broader, managed care plans.

While federal law does not require medication synchronization by QHPs, beginning in 2014, the Centers for Medicare and Medicaid Services requires health plans administering Medicare Part D plans to apply a daily cost-sharing rate to most prescriptions that are dispensed for less than a 30-day supply.[22]

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[13] Oh. Rev. Stat. ss. 1751.68 and 3923.602.
[14] The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. P.L. 111-148. Most of the insurance regulatory provisions in PPACA amend Title XXVII of the Public Health Service Act, 42 U.S.C. s. 300gg et seq.
[15] 42 U.S.C. s. 18022; 45 CFR s. 156.110 et seq.
[16] Id., see also, Centers for Medicare and Medicaid Services, *Information on Essential Health Benefits (EHB) Benchmark Plans,* available at: https://www.cms.gov/cciio/resources/data-resources/ehb.html (last visited March 23, 2017).
[17] Center for Consumer Information & Insurance Oversight, *Qualified Health Plans,* available at: https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/qhp.html (last visited March 25, 2017).
[18] The Patient Protection and Affordable Care Act (Pub. L. 111–148). This regulation does not apply to large group plans, self-insured plans, transitional plans, or grandfathered plans.
[19] 45 C.F.R. s. 156.135.
[20] 45 C.F.R. s. 156.122(e).
[21] P.L. 108-173.
[22] Centers for Medicare and Medicaid Services, *Medicare Part D Overutilization Monitoring System – Updates*, (Oct. 25, 2013), available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoMedicare-Part-D-OMS-Updates-10-25-13.pdf (last visited March 25, 2017); Centers for Medicare and Medicaid Services, *Copayment/coinsurance in drug plans*, available at:https://www.medicare.gov/part-d/costs/copayment-coinsurance/drug-plan-copayments.html (last visited March 25, 2017).

Regulation of Insurance in Florida

Regulation of Health Insurers and Health Maintenance Organizations

The regulatory oversight of insurance companies is generally reserved to the states. In Florida, the Office of Insurance Regulation (OIR) is responsible for all activities concerning insurers and other risk bearing entities, as provided under the insurance code. OIR regulates health insurer provider contracts under part VI of ch. 627, F.S. and health maintenance organization (HMO) contracts and rates under part I of ch. 641, F.S. To operate in Florida, an HMO must obtain a certificate of authority from OIR.[23] The Agency for Health Care Administration (AHCA) regulates the quality of care provided by HMOs under part III of ch. 641, F.S. Before receiving a certificate of authority from OIR, an HMO must receive a Health Care Provider Certificate from AHCA.[24]

The Florida Insurance Code requires health insurers and HMOs to provide an outline of coverage or other information describing the benefits, coverages, and limitations of a policy or contract. This may include an outline of coverage, including prescription drug coverage, describing the principal exclusions and limitations of the policy.[25] Section 641.31(4), F.S., requires each contract, certificate, or member handbook of an HMO to delineate the services, including prescription drug coverage, for which a subscriber is entitled and any limitations under the contract.

Pharmacy Benefit Managers

Health insurers and HMOs contract with pharmacy benefit managers (PBMs) to help manage prescription drug benefits. PBMs are sometimes referred to as the middlemen in the prescription drug market because they act as intermediaries between health plan sponsors and drug manufacturers and pharmacies.[26] PBMs provide specified services, which may include developing and managing pharmacy networks, developing drug formularies, providing mail order and specialty pharmacy services, providing support services for physicians and beneficiaries, and processing claims.[27] Their contracts with PBMs also establish how pharmacies will be reimbursed for prescriptions they dispense to health plan sponsor beneficiaries.[28]

State Employees' Prescription Drug Program

The State Group Insurance Program (SGI Program) was created by s. 110.123, F.S., and is administered by the Division of State Group Insurance within the Department of Management Services (DMS). The SGI Program is an optional benefit for all state employees including all state agencies, state universities, the court system, and the Legislature, and includes health, life, dental, vision, disability, and other supplemental insurance benefits.

As part of the SGI Program, DMS is required to maintain the State Employees' Prescription Drug Program (Prescription Drug Plan).[29] DMS contracts with CVS/Caremark, a PBM, to administer the Prescription Drug Plan.[30] A member can receive up to a 30-day supply of prescription medication at a retail pharmacy in the Prescription Drug Plan network and up to a 90-day supply at a mail order pharmacy or at a participating 90-day retail pharmacy.

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[23] S. 641.21(1) and 641.49, F.S.
[24] S. 641.21(1) and 641.48, F.S.
[25] S. 627.642, F.S.
[26] Office of Program Policy Analysis & Government Accountability, *Legislature Could Consider Options to Address Pharmacy Benefit Manager Business Practices*, Report No. 07-08 (Feb. 2007), available at: http://www.oppaga.state.fl.us/MonitorDocs/Reports/pdf/0708rpt.pdf (last visited March 25, 2017).
[27] Id.
[28] Id.
[29] S. 110.12315, F.S.
[30] Department of Management Services, *myFlorida, Prescription Drug Plan*, available at: http://mybenefits.myflorida.com/health/health_insurance_plans/prescription_drug_plan (last visited March 25, 2017).

Currently, the SGI Program does not allow for the synchronization of medication if it requires an early refill.

Effect of Proposed Changes

CS/HB 1191 requires certain health insurers and HMOs to offer medication synchronization services on all policies entered into or renewed on or after January 1, 2018. The medication synchronization services must allow an insured or subscriber to align refill dates of his or her covered prescription drugs at least once per year; however, they may elect to offer this service to their insureds or subscribers more frequently if they so choose. Health insurance policies and HMO contracts that provide prescription drug coverage must cover a partial supply of a covered prescription medication dispensed by a network pharmacy at a prorated cost-sharing for medication synchronization.

This will allow patients, at least once per year, to obtain a partial refill to align their medications, without incurring any additional costs for refilling too soon or having to pay more than the prorated rate for a partial refill. Aligning prescription refill dates will necessitate fewer trips to the pharmacy for refills, which may reduce gaps in therapies because of improved adherence to prescription medication regimens.

The bill limits the types of prescription drugs are eligible for a partial refill under medication synchronization. It prohibits a partial fill to align refill dates for the following prescription drugs:

- Controlled substances;
- Prescription drugs dispensed in unbreakable packages; and
- Multi-dose units of prescription drugs.

Additionally, the bill requires a health insurer or HMO to pay the pharmacy in full for each prescription dispensed, unless otherwise agreed to at the time an insured or subscriber requests medication synchronization. Health insurers and HMOs may have to update their contracts with pharmacies or PBMs for how they reimburse for partial prescription refills to allow the pharmacy gets a full dispensing fee when the partial refill is for medication synchronization.

The bill provides an effective date of July 1, 2017.

B. SECTION DIRECTORY:

Section 1: Creates s. 627.64196, F.S., relating to medication synchronization.
Section 2: Amends s. 641.31, F.S., relating to health maintenance contracts.
Section 3: Provides an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   For each partial refill made for the purpose of medication synchronization, DMS expects an initial low-cost negative fiscal impact to the SGI Program. However DMS anticipates greater member adherence to prescription medication regimens for chronic conditions, which should result in overall lower medical spending in the SGI Program

DMS will need to make changes to the summary plan description currently used by the SGI Program's PBM to allow for prescriptions to be filled at any point for medication synchronization.[31] DMS would also need to develop and incorporate a proration schedule outlining and creating prorated copayment amounts for medication synchronization.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:
None.

2. Expenditures:
None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

There may be new administrative costs for insurers and pharmacies to institute daily cost sharing rates for partial fills and refills.[32] Some insurers may also incur costs to revise their forms to comply with the bill.[33] Insurers may have to renegotiate or amend their contracts with PBMs to take into account the bill's requirements.

D. FISCAL COMMENTS:

For SGI Program members with a Preferred Provider Organization plan filling maintenance medications at a retail pharmacy, any "partial" fill would count as one of their three 30-day fills at retail before being required to use 90-day retail refill or 90-day mail order refill.[34]

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

S. 110.12315(11), F.S., may need to be amended to incorporate provisions regarding prorated member cost-share for medication synchronization in the Prescription Drug Plan.

[31] Department of Management Services, *Agency Analysis of 2017 House Bill 1191* (Mar. 12, 2017) (on file with Health Innovation Subcommittee staff).
[32] Office of Insurance Regulation, *Agency Analysis of 2017 House Bill 1191* (Mar. 7, 2017) (on file with Health Innovation Subcommittee staff).
[33] Id.
[34] Supra, FN 31.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 27, 2017, the Health Innovation Subcommittee adopted a strike-all amendment that:

- Required health insurance policies and HMOs to implement a policy that offers medication synchronization services for covered prescription drugs at least once per plan year;
- Prohibited medication synchronization for controlled substances, prescription drugs dispensed in unbreakable packages, and multi-dose units of a prescription drug; and
- Made the bill applicable to policies renewed or entered into on or after January 1, 2018.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.